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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/642,844 | 08/18/2003 | Alfred J. Lewy | 90,559-T | 3196 |

7590 03/16/2009

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|---|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/16/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/642,844 | LEWY ET AL. | |
| | Examiner | Art Unit | |
| | Leslie A. Royds | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 Jun 08; 21 Aug 08; and 09 Dec 08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-8,11-17 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04Jun08; 11July08; 21Aug08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-24 are presented for examination.**

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed June 4, 2008 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Pursuant to the notice dated August 13, 2008, Applicant's submission filed June 4, 2008 was non-compliant. Applicant's submission filed August 21, 2008 correcting these deficiencies was received and entered into the present application, but was also found to be non-compliant pursuant to the notice dated December 2, 2008. Applicant's subsequent submission filed December 9, 2008 has been received and entered into the present application.

Applicant's Information Disclosure Statements (IDS) filed June 4, 2008 (three pages); July 11, 2008 (two pages) and August 21, 2008 (two pages) have each been received and entered into the present application. The information disclosure statements filed June 4, 2008 and July 11, 2008 each failed to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicant failed to provide copies of any of the non-patent literature documents cited therein and, thus, the information disclosure statements of June 4, 2008 and July 11, 2008 were not further considered.

Furthermore, Applicant's Information Disclosure Statement (IDS) filed August 21, 2008 has also been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (two pages total), the Examiner has considered the cited references, with the exception

of Cite Nos. 4 and 6 on the IDS filed August 21, 2008, which does not contain a date of publication and, thus, fail to comply with the requirements of MPEP §609. The references have been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this IDS or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 C.F.R. 1.97(e). See MPEP §609.05(a).

Claims 1-24 are pending. Claims 1-8, 11-17 and 20-24 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) as being directed to non-elected subject matter. Claims 9-10 and 18-19 are under examination. Claim 9 is amended.

Applicant's arguments, filed June 4, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewy et al. (WO 95/05819; 1995), already of record, for the reasons of record set forth at p.6-8 of the previous Office Action dated December 4, 2007, of which said reasons are herein incorporated by reference.

Newly amended claim 9 remains properly included in the present rejection because Lewy et al. teaches a method for treating circadian rhythm phase disturbances (abstract) by effecting a chronobiologic (phase-shifting) effect in a human via the administration of exogenous melatonin to the human at an appropriate time relative to the human's dim light endogenous melatonin onset time (p.5, l.23-27). Lewy et al. further discloses the treatment of jet lag as a preferred embodiment (p.8, l.15-18), and also teaches that the direction of the travel will determine whether a phase advance or a phase delay is desired (p.25, l.13-15). Lewy et al. teaches that melatonin administration should occur preferably between CT20 to about CT2 and most preferably at about CT0 in order to effect a phase delay (p.8, l.3-5) and also discloses the use of melatonin precursors, agonists or compounds that mimic melatonin activity in place of melatonin itself (p.6, l.12-14).

Though Lewy et al. does not explicitly teach (1) that the administration of the melatonin (or a melatonin agonist or compound that increase endogenous production of melatonin) produces in the human a plasma melatonin or agonist concentration of greater than quiescent melatonin or equivalent agonist levels during the time interval from about CT18 to about CT6 than from the time interval from about CT6 to about CT18 or (2) wherein plasma melatonin or equivalent agonist levels are elevated during a time interval that overlaps CT0, the administration of the same compound as claimed (i.e., melatonin or agonist thereof) to a human suffering from jet lag is considered to necessarily have the claimed effect on plasma melatonin levels from CT18-CT6 than from CT6-CT18, whether expressly recognized by Lewy et al. or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances in the same host in the same amount. See MPEP §2112.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the effects on plasma melatonin levels was not itself recognized as a pharmacological

effect of administering melatonin or an agonist thereof of Lewy et al. to a human suffering from jet lag, such an effect is not considered a new therapeutic application because the known treatment of jet lag using this same active agent was already known in the prior art. Though mechanisms of action or functional effects of chemical entities are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 is based upon the therapeutic applications and therapeutic effects of the compounds, not the mechanism or functional property by which they exert such an effect. Furthermore, it is generally well settled in the courts that a mechanistic property or functional effect of a chemical compound, or combination of chemical compounds, when administered under identical conditions to identical hosts, is necessarily present, despite the fact that it may not have been readily apparent to, or recognized by, one of ordinary skill in the art.

*In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions and/or properties that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function and/or property at the time of invention, so long as the function and/or property can be demonstrated to be reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). In the instant case, though Lewy et al. may not expressly teach that the plasma melatonin concentration from CT18-CT6 is greater than from the

time interval from CT6-CT18 or that the plasma melatonin levels are elevated during a time interval that overlaps CT0, the prior art to Lewy et al. execute the same method steps for the same purpose of rendering a phase-delaying effect using the same compounds, and, therefore, the resultant plasma concentrations must also be the same, absent factual evidence to the contrary. The burden is now shifted to Applicant to prove that, in fact, Lewy et al. does not possess these same claimed characteristics.

*Response to Applicant's Arguments*

Applicant traverses the instant rejection, stating that Lewy teaches a broader time interval for melatonin administration to achieve a phase delay between CT12 to CT6 than is taught and claimed in the instant application (i.e., CT18 to CT6). Applicant submits that, while Lewy et al. teaches melatonin administration between CT12 and CT6, there is no teaching that the period of elevated physiological melatonin concentration should extend past the endogenous melatonin offset (i.e., CT0), nor any teaching to have higher melatonin concentration during one part of the phase response curve (i.e., the 12-hr interval from CT18 to CT6). Applicant insists that Lewy et al. contains no teaching of maintaining elevated plasma melatonin levels to extend past a human's endogenous melatonin offset time (CT0) to effect a phase delay in the human phase response curve, nor does it teach that the plasma melatonin concentration should be higher over the interval from CT18-CT6 than in the interval from CT6 to CT18. In fact, Applicant submits that, in view of the limited melatonin dosage amounts taught in Lewy et al., it is "likely that overall the integrated levels of melatonin (endogenous and exogenous) in the time periods of CT6 and CT18 are greater than in the interval from CT18 to CT6" (p.13, Remarks) or that there was little likelihood that elevated melatonin would extend past the endogenous melatonin offset time (CT0; p.13, Remarks). Applicant further relies upon the claims issued in U.S. Patent No. 6,638,936 as evidence that the instant rejection should be withdrawn.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant's arguments that the instant claims distinguish over the prior art because Lewy teaches a broader time interval for melatonin administration to achieve a phase delay between CT12 to CT6 than that claimed in the instant application (i.e., CT18-CT6) is unpersuasive. Though the disclosure of a phase delay between CT12 and CT6 may very well be broader than the instantly claimed interval between CT18 and CT6, the fact remains that the teachings of Lewy et al. do, contrary to Applicant's allegations, achieve a phase delay between CT18 and CT6 in view of the teaching that Lewy et al. discloses administration of melatonin (or melatonin precursors, agonists or compounds that mimic melatonin activity in place of melatonin itself; see p.6, l.12-14) between CT12 and CT6 (p.7, l.17-19), preferably between CT20 and CT2 (p.7, l.25-29). The administration of melatonin between CT20 and CT2 clearly falls within the range of CT18-CT6 as instantly claimed and, thus, meets this claimed limitation. The fact that the Lewy et al. may also disclose a range that is broader than Applicant's claimed range is immaterial to the fact that the reference does clearly teach an interval of administration that falls within Applicant's instantly claimed range and, thus, anticipates this limitation.

Secondly, Applicant's argument that Lewy et al. does not teach that the period of elevated physiological melatonin concentration should extend past the endogenous melatonin offset time (i.e., CT0) is similarly unpersuasive. The instant claims do not require the elevation of physiological melatonin is *maintained* over a time interval that overlaps CT0, but rather solely requires that the plasma melatonin or equivalent agonist levels are elevated *during a time interval that overlaps CT0*. As above, this is clearly met by the teachings of Lewy et al., who discloses administration of melatonin (or melatonin precursors, agonists or compounds that mimic melatonin activity in place of melatonin itself; see p.6, l.12-14) between CT12 and CT6 (p.7, l.17-19), preferably between CT20 and CT2 (p.7, l.25-29). Thus, the administration of melatonin (or its precursors, agonists, etc.) between CT20 and CT2 would clearly result in an elevated plasma melatonin or equivalent agonist level for at least one, if not more than one, timepoint during this same time interval that overlaps CT0.

Thirdly, Applicant's argument that Lewy et al. also does not teach a higher melatonin concentration during one part of the phase response curve (i.e., the 12-hr interval from CT18 to CT6) is unpersuasive. Lewy et al. explicitly discloses that, for a *phase delay*, such as that which would be desired during travel to offset jet lag, the melatonin (or melatonin precursors, agonists, or compounds that mimic melatonin activity in place of melatonin itself) should be administered between CT12 and CT6, preferably between CT20 and CT2. Thus, the administration of melatonin (or its precursors, agonists, etc.) between CT20 and CT2 would clearly result in a higher melatonin concentration during this latter part of the circadian clock and also, notably, clearly falls within the range of CT18-CT6 as instantly claimed. Note, again, as stated *supra*, that the instant claims do not require the greater plasma melatonin or agonist concentration to be *maintained* over the time interval from CT18 to CT6, but rather solely require that the plasma melatonin or equivalent agonist levels be greater during the time interval of CT18-CT6 than from the time interval from CT6-CT18, which is met by Lewy's teaching of melatonin (or its precursors, agonists, etc.) between the time interval of CT20-CT2. This elevated melatonin concentration as a result of exogenous melatonin administration during CT20-CT2 clearly supports the interpretation that the plasma melatonin concentration between CT18-CT6 is greater than that found within the time interval of CT6-CT18.

Fourthly, Applicant's argument again that Lewy et al. contains no teaching of maintaining elevated plasma melatonin levels to extend past a human's endogenous melatonin offset time (CT0) to effect a phase delay in the human phase response curve or a teaching that the plasma melatonin concentration should be higher over the interval from CT18-CT6 than in the interval from CT6-CT18 is unimpressive. As described *supra*, the instant claims do not recite any requirement that the plasma melatonin levels be *maintained* over the time interval of CT18-CT6 to result in a greater plasma melatonin concentration during this time interval, nor do they recite any requirement that the elevated plasma melatonin level be *maintained* over a time interval that overlaps CT0. The instant claims solely

require (1) the plasma melatonin level to be greater *during* the time interval of CT18-CT6 and (2) the plasma melatonin level to be elevated *during* a time interval that overlaps CT0, which is clearly met by Lewy et al. [who teaches administration of melatonin (or precursors, agonists, etc.) during CT20-CT2, which would result in greater plasma melatonin levels *during* CT18-CT6, which overlaps CT0]. Accordingly, Applicant is attempting to patentably distinguish the instant claims over the cited prior art to Lewy et al. by arguing limitations that are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As a result, such arguments are clearly found unpersuasive.

Fifthly, Applicant alleges that, in view of the limited melatonin dosage amounts taught in Lewy et al., it is "likely that overall the integrated levels of melatonin (endogenous and exogenous) in the time periods of CT6 and CT18 are greater than in the interval from CT18 to CT6" (p.13, Remarks) or that there was little likelihood that elevated melatonin would extend past the endogenous melatonin offset time (CT0). This is unpersuasive. Counsel's assertions that Lewy et al. would result in a greater level of melatonin during the time interval CT6-CT18 than from CT18-CT6 or that the elevated melatonin would not extend past the endogenous melatonin offset time are unsupported allegations and fail to take the place of evidence in the record, particularly because Applicant has not fulfilled his burden of actually *demonstrating* that this is actually the case. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP §2145, which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)." Applicant has failed to proffer any comparison between the prior art to Lewy et al. and that of the instantly claims to support his allegation that the cited prior art, in fact, does, as he alleges, result in a greater level of melatonin during the time interval CT6-CT18 than from CT18-CT6 or that the elevated melatonin would not extend past

the endogenous melatonin offset time. Without these facts, Applicant's arguments amount to no more than speculation of what would occur from the disclosure of the prior art and do not take the place of actual evidence in the record.

Sixthly, and lastly, Applicant's reliance upon the claims issued in U.S. Patent No. 6,638,936 as evidence that the instant rejection should be withdrawn is unimpressive. The claims are distinct from those instantly under examination and, therefore, the fact that such claims have been allowed is immaterial to the patentability of the presently claimed subject matter. Moreover, each case before the Office is decided on its own merits. Decisions made during the course of prosecution of previous applications (including those that ultimately result in a patent) are not binding to the course of prosecution of any other application pending before the Patent and Trademark Office.

For these reasons *supra*, and those previously made of record at p. 6-8 of the Office Action dated December 4, 2007, rejection of claims 9-10 and 18-19 remains proper and is **maintained**.

### *Double Patenting (New Grounds of Rejection)*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44-48 and 59 of U.S. Patent Application No. 10/945,843 and remain rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 4-5, 9, 12-13 and 45 of U.S. Patent No. 5,591,768; or claims 1-3, 9 and 11

of U.S. Patent No. 5,716,978; or claims 1, 3-5, 7 and 9-10 of U.S. Patent No. 6,638,963; or claims 1-2 and 4 of U.S. Patent No. 6,794,407.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending application are not considered patentably distinct from each other because the pending claims are rendered obvious by the copending claims.

The copending and/or patented claims each clearly provide for the treatment of jet lag via achieving a circadian rhythm phase-delaying effect in a human by administering melatonin, a melatonin agonist or a compound that increases endogenous production of melatonin in the human at a time after CT18 and prior to CT1. Note that, though the claims of the '978 patent do not specifically recite the treatment of jet lag *per se*, the patent specification clearly defines jet lag as one of the conditions resulting in a need for a phase shift of circadian rhythm. See col.4, l.52. Please note that, in the instant case, the disclosure of the copending patent application is being relied upon solely to define the meaning of the human with a free-running circadian rhythm that is out of synchrony with the external environment that is treated via the patented claims, which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patient claim. *Toro Co. v. White Consol. Indus., Inc.* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

Though the copending and/or patented claims do not explicitly teach (1) that the administration of the melatonin (or a melatonin agonist or compound that increase endogenous production of melatonin) produces in the human a plasma melatonin or agonist concentration of greater than quiescent melatonin or equivalent agonist levels during the time interval from about CT18 to about CT6 than from the time

interval from about CT6 to about CT18 or (2) wherein plasma melatonin or equivalent agonist levels are elevated during a time interval that overlaps CT0 as instantly claimed, the administration of the same compound as claimed (i.e., melatonin or agonist thereof) to a human suffering from jet lag at the same time (i.e., after CT18 and prior to about CT1) is considered to necessarily have the claimed effect on plasma melatonin levels from CT18-CT6 than from CT6-CT18, whether expressly recognized by the copending and/or patented claims or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances (i.e., same time, etc.) in the same host in the same amount. See MPEP §2112. It is generally well settled in the courts that a mechanistic property or functional effect of a chemical compound, or combination of chemical compounds, when administered under identical conditions to identical hosts, is necessarily present, despite the fact that it may not have been readily apparent to, or recognized by, one of ordinary skill in the art.

Accordingly, rejection of claims 9-10 and 18-19 is proper over claims 1, 4-5, 9, 12-13 and 45 of U.S. Patent No. 5,591,768; or claims 1-3, 9 and 11 of U.S. Patent No. 5,716,978; or claims 1, 3-5, 7 and 9-10 of U.S. Patent No. 6,638,963; or claims 1-2 and 4 of U.S. Patent No. 6,794,407 and is also proper over claims 44-48 and 59 of U.S. Patent Application No. 10/945,843 as claiming obvious and unpatentable variants thereof.

This is a provisional rejection over the '843 application because the claims in this case have not yet, in fact, been patented.

Claims 9 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 9-11 of U.S. Patent No. 5,242,941 or claims 1 and 3 of U.S. Patent No. 5,420,152.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are

not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited copending application are not considered patentably distinct from each other because the pending claims are rendered obvious by the copending claims.

The copending and/or patented claims each clearly provide for the treatment of jet lag via achieving a circadian rhythm phase-delaying effect in a human by administering melatonin, a melatonin agonist or a compound that increases endogenous production of melatonin in the human. Note that, though the claims of the '941 patent or the '152 patent do not specifically recite the treatment of jet lag *per se*, the copending specification clearly defines jet lag as one of the conditions resulting in a need for a phase shift of circadian rhythm. See col.4, l.60 of the '941 patent and col.4, l.65 of the '152 patent. Please note that, in the instant case, the disclosure of the copending patent application is being relied upon solely to define the meaning of the conditions requiring a phase-shift in human circadian rhythm that is treated via the patented claims, which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patient claim. *Toro Co. v. White Consol. Indus., Inc.* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

Though the patented claims do not explicitly teach (1) that the administration of the melatonin (or a melatonin agonist or compound that increase endogenous production of melatonin) produces in the human a plasma melatonin or agonist concentration of greater than quiescent melatonin or equivalent agonist levels during the time interval from about CT18 to about CT6 than from the time interval from about CT6 to about CT18 or (2) wherein plasma melatonin or equivalent agonist levels are elevated during a time interval that overlaps CT0 as instantly claimed, the administration of the same compound as claimed (i.e., melatonin or agonist thereof) to a human suffering from jet lag is considered to necessarily

have the claimed effect on plasma melatonin levels from CT18-CT6 than from CT6-CT18, whether expressly recognized by the copending and/or patented claims or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances (i.e., same time, etc.) in the same host in the same amount. See MPEP §2112. It is generally well settled in the courts that a mechanistic property or functional effect of a chemical compound, or combination of chemical compounds, when administered under identical conditions to identical hosts, is necessarily present, despite the fact that it may not have been readily apparent to, or recognized by, one of ordinary skill in the art.

Accordingly, rejection of claims 9 and 18-19 is proper over claims 1, 4-6 and 9-11 of U.S. Patent No. 5,242,941 or claims 1 and 3 of U.S. Patent No. 5,420,152 as claiming obvious and unpatentable variants thereof.

*Response to Applicant's Arguments Regarding the Rejection over U.S. Patent No. 6,638,963*

Applicant traverses the instant rejection over the '963 patent, stating that the '963 patent issued from U.S. Patent Application No. 08/840,382 and the Office determined during prosecution of this prior application that the claims of the instant application are patentably distinct. Applicant then concludes that the Office cannot now require that he submit a Terminal Disclaimer because this would contradict the earlier determination in the '382 application.

This argument is unpersuasive in establishing error in the present obviousness-type double patenting rejection of the instant claims over those of the '963 patent. A review of the original claims presented in the '382 application and those originally filed in the instant claims shows that the instant claims were not strictly commensurate in scope with those claims determined to be patentably distinct in the '382 application. For example, the instant claims recite several functions resulting from the administration of melatonin that were not pending in the original '382 claims (i.e., that the plasma

melatonin or equivalent agonist levels are elevated during a time interval that overlaps CT0, or that the administration produces in the human a plasma melatonin or agonist concentration of greater melatonin or equivalent agonist levels during the time from about CT18 to about CT6 than from the time interval from about CT6 to about CT18). Furthermore, the claims of the '382 that are even closest (though not admitted by the Examiner to be identical to the instant claims) to the subject matter now claimed are also generic to a "phase-shifting" effect, and are not specific to the "phase-delay" as instantly claimed. Moreover, such claims of the '382 also do not provide for the administration of the melatonin specifically after about CT18 and prior to about CT1.

An obviousness-type double patenting rejection would be precluded if the instant claims filed in the instant application were filed as a direct result of the restriction requirement made in the '382 application and constituted one of the various patentably distinct but non-elected inventions of this '382 application. In view of the reasons *supra*, it is clear that the instant claims are not strictly commensurate with one of the various patentably distinct but non-elected inventions of this '382 application and, thus, the obviousness-type double patenting rejection over the '963 patent is not precluded as a result of the restriction requirement made in the '382 application.

If Applicant has specific reasons for asserting that the rejection is improper, he is invited to clearly set such reasons forth on the record by analyzing the original claims filed and restricted in the '382 application and how they correspond to the claims originally filed in the instant application.

***Conclusion***

Rejection of claims 9-10 and 18-19 remains proper.

Claims 1-8, 11-17 and 20-24 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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March 9, 2009

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